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Proposed Maximum Residue Limit PMRL2013-52

Fluopyram

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has granted conditional registration to technical grade fluopyram and the end-use products Luna Privilege, containing technical grade fluopyram, Luna Tranquility Fungicide, containing technical grade fluopyram and pyrimethanil, and Propulse Fungicide, containing technical grade fluopyram and prothioconazole, for use in Canada on various crops. The specific uses approved in Canada are detailed on the product labels of Luna Privilige, Luna Tranquility Fungicide and Propulse Fungicide, *Pest Control Products Act* Registration Numbers 30509, 30510 and 30511, respectively.

The evaluation of these fluopyram applications indicated that the end-use products have merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

In addition, the PMRA is proposing to establish MRLs for fluopyram on bananas and sugar beet roots to permit the import and sale of food containing such residues. The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when fluopyram is used according to label directions in the exporting country, and that such residues will not be a concern to human health.

Consultation on the proposed MRLs for fluopyram is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

The currently established MRL of 0.9 ppm in/on dry chickpeas, dry lentils and dry beans for prothioconazole, and 14 ppm in/on apples and 5 ppm in/on grapes for pyrimethanil are sufficient to cover residues resulting from this new use, and are therefore unaffected by this MRL action.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs for fluopyram are as follows.

Table 1 Proposed Maximum Residue Limits for Fluopyram

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Fluopyram	N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide	2.0	Grapes
		1.8	Rapeseeds (canola)
		1.5	Crop Group 15, except rice (Cereal grains, except rice); Sweet cherries; Tart cherries; Strawberries
		1.0	Bananas; Watermelon
		0.4	Dry chickpeas; Dry lentils
		0.3	Apples
		0.1	Sugar beet roots; Dry soybeans
		0.09	Dry beans
		0.05	Crop Group 14 (Tree Nuts); Pistachios
		0.02	Crop Subgroup 1C (Tuberous and corm vegetables); Peanuts
		0.01	Undelinted cotton seeds
	N-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide including the metabolite 2-(trifluoromethyl)benzamide (expressed as parent equivalent)	0.4	Meat byproducts of cattle, goats, horses and sheep
		0.1	Meat byproducts of poultry
		0.06	Eggs; Milk
		0.05	Fat and meat of cattle, goats, horses and sheep
		0.03	Meat byproducts of hogs; Fat and meat of poultry
		0.02	Fat and meat of hogs

ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for fluopyram in Canada with the corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian and Codex MRLs and American Tolerances (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Canola	1.8	1.8 (indirect residues)	Not established
Crop Group 15, except rice (Cereal grains, except rice)	1.5	1.5 (indirect residues)	Not established
Cherries	1.5	0.60	Not established
Strawberries	1.5	1.5	Not established
Bananas	1.0	1.0	Not established
Watermelon	1.0	1.0	Not established
Dry chickpeas and dry lentils	0.4	Not established	Not established
Apples	0.3	0.30	Not established
Sugar beet roots	0.1	0.04	Not established
Soybeans	0.1	0.10 (indirect residues)	Not established
Dried beans	0.09	0.09	Not established
Crop Group 14 (Tree Nuts) and pistachios	0.05	0.05	Not established
Crop Subgroup 1C (Tuberous and corm vegetables)	0.02	0.02 (potato)	Not established
Peanuts	0.02	0.02	Not established
Undelinted cotton seeds	0.01	0.01 (indirect residues)	Not established
Fat and meat of cattle, goats, horses and sheep	0.05	0.11 (fat), 0.15 (meat)	0.1 (meat from mammals other than marine mammals), 0.7 (edible offal, mammalian)
Meat byproducts of cattle, goats, horses and sheep	0.4	1.1	
Fat and meat of hogs	0.02	0.05	
Meat byproducts of hogs	0.03	0.70	
Fat and meat of poultry	0.03	0.20 (fat), 0.15 (meat)	Not established
Meat byproducts of poultry	0.1	0.60	Not established
Eggs	0.06	0.25	Not established
Milk	0.06	0.07	0.07

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fluopyram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data from supervised residue trials conducted in the United States and Canada on potatoes, beans, peas, melons, apples, cherries, grapes, strawberries, almond, pecans, peanuts, field corn, wheat, sorghum, canola, soybean and were submitted to support the domestic use of fluopyram on these crop commodities, and residue data for fluopyram in bananas, sugar beets and cotton (as a rotational crop) were submitted to support the establishment of maximum residue limits on imported crops. Fluopyram was applied to crops at label rates or exaggerated rates, and harvested according to label directions. In addition, processing data on treated apples, canola, corn, cotton, grapes, peanuts, potatoes, soybeans, strawberries, sugar beets and wheat were reviewed to determine the potential for concentration of residues of fluopyram into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fluopyram was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the data used to calculate the proposed MRLs for tuberous and corm vegetables (Crop Subgroup 1C), tree nuts (Crop Group 14), cereal grains, except rice (Crop Group 15, except rice), apples, bananas, canola, cherries, dry beans, dry chickpeas, dry lentils, peanuts, soybeans, strawberries, sugar beet roots, undelinted cotton seeds, watermelon and wine grapes. Residues in processed commodities not listed in Table 1 are covered under the recommended MRLs for the raw agricultural commodities (RACs).

TABLE A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Fluopyram Residues (ppm)		Experimental Processing Factor
			Min	Max	
Potatoes	Foliar/ 500	6-7	<0.01	0.017	No concentration observed in potato flakes and chips
Sugar beet roots	Foliar/ 500	6-7	0.013	0.050	1.3x in refined sugar; no concentration observed in molasses
Dry beans	Foliar/ 500	13-14	<0.01	0.076	Not required
Dry peas	Foliar/ 500	13-14	0.03	0.350	Not required
Muskmelons	Foliar/ 500	0	0.069	0.529	Not required
Apples	Foliar/ 500	7	0.040	0.262	No concentration observed in apple juice
Cherries	Foliar/ 500	0	0.066	1.229	Not required
Grapes	Foliar/ 439-513	6-7	0.096	0.950	3.0x in raisins; no concentration observed in grape juice
Strawberries	Drip irrigation/ 495-525	7	<0.01	0.244	Not required
Almonds	Foliar/ 500	14	<0.01	0.019	Not required
Pecans	Foliar/ 500	14	<0.01	0.045	Not required
Peanuts	Foliar/ 500	7	<0.01	0.018	No concentration observed in peanut oil
Bananas	Foliar/ 600	0	0.018	0.526	Not required
Field corn grain*	Foliar/ 500	11-14	<0.01	0.020	2.6x in bran; no concentration observed in corn meal and oil
Sweet corn ears*	Foliar/ 500	0	<0.01	<0.01	Not required
Wheat grain*	Foliar/ 500	14	0.037	0.764	2.7x in bran; 2.4x in germ; no concentration observed in wheat flour
Sorghum grain*	Foliar/ 500	14	0.23	3.24	Not required
Canola seeds*	Foliar/ 500	12-14	0.089	3.00	No concentration observed in canola meal and oil
Soybean seeds*	Foliar/ 500	14	<0.01	0.180	No concentration observed in soybean meal and oil
Cotton seeds (rotational data)	Foliar to soil/ 495-511	12-14	<0.01	<0.01	No concentration expected in cotton meal and oil

PHI = preharvest interval

* The highly conservative primary crop residue data on these crops were used to propose MRLs for rotational crops. The confined accumulation data, limited field rotational crop data and primary crop data for the target rotational crops were examined to select an intermediate level so as to discourage potential misuse and provide adequate maximum residue levels for legal uses according to label directions. The foliar residues in wheat commodities ranged from 2.7× (wheat straw) to 76× (wheat grain) when compared to the confined accumulation and limited field residue data. Thus, pending extensive field rotational crop data, it was recommended to set the MRLs in/on rotational crops at half of the calculated primary crop MRL with a plant-back interval of 30 days.

Based on the dietary burden and residue data, MRLs of 0.4 ppm in meat byproducts of cattle, goats, horses and sheep; 0.1 ppm in meat byproducts of poultry; 0.06 ppm in eggs and milk; 0.05 ppm in fat and meat of cattle, goats, horses and sheep; 0.03 ppm in meat byproducts of hogs, and fat and meat of poultry; and 0.02 ppm in fat and meat of hogs are also proposed to cover fluopyram including the metabolite 2-(trifluoromethyl)benzamide (expressed as parent equivalent).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fluopyram. Residues of fluopyram in these crop and livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.